

The listing of claims presented below replaces all prior versions and listings of claims in the application.

Listing of Claims

Cancel claims 1-44.

45. (Currently Amended) A stable pharmaceutical composition comprising a therapeutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug or a pharmaceutically acceptable salt, solvate or derivative thereof selected from group consisting of:

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

~~S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid 0.2 hydrate; and~~

RS-(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid; and

a pharmaceutically acceptable solubilizing agent selected from a the group consisting of basic amino acids, a cyclodextrin and, a cyclodextrin polymer; or a mixture thereof;

wherein the concentration of the drug that is maintained in solution with the solubilizing agent is above the practical limit of solubility of the drug as compared to the solubility of the drug when the drug is not in solution with the solubilizing agent, wherein the solution is a substantially isotonic aqueous solution at a physiologically compatible pH.

46. (Previously Presented) The composition of claim 45, wherein the concentration of the drug

is about 1 mg/ml to about 100 mg/ml.

47. (Previously Presented) The composition of claim 45, wherein the concentration of the drug is about 4 mg/ml to about 12 mg/ml.

48. (Previously Presented) The composition of claim 45, wherein the concentration of the drug is about 5 mg/ml to about 9 mg/ml.

49. (Previously Presented) The composition of claim 45, wherein the amino acid is selected from arginine, histidine, arginine acetate, arginine-glutamate, arginine monohydrochloride, histidine acetate, histidine acetate dihydrate, histidine monohydrochloride, histidine monohydrochloride monohydrate, lysine, lysine acetate, lysine monohydrochloride, ornithine, tryptophan or a salt thereof.

50. (Previously Presented) The composition of claim 45, wherein the amino acid is L-arginine.

51. (Previously Presented) The composition of claim 45, wherein the cyclodextrin polymer is selected from the group consisting of  $\alpha$ -cyclodextrin,  $\beta$ -cyclodextrin,  $\gamma$ -cyclodextrin, and hydroxypropyl  $\beta$ -cyclodextrin.

52. (Previously Presented) The composition of claim 45, wherein the cyclodextrin polymer is hydroxypropyl  $\beta$ -cyclodextrin.

53. (Previously Presented) The composition of claim 45, wherein the solubilizing agent comprises from about 1.5 % to about 3.5 % by weight of the composition.

54. (Previously Presented) The composition of claim 45, wherein the solubilizing agent is an amino acid and comprises about 0.1 % to about 1.4 % by weight of the composition.

55. (Previously Presented) The composition of claim 45, wherein the solubilizing agent is cyclodextrin polymer and comprises about 1.5 % to about 3.5 % by weight of the composition.

56. (Previously Presented) The composition of claim 45, that is suitable for parenteral administration.

57.(Previously Presented) The composition of claim 45, that is suitable for intravenous injection or infusion.

58.(Previously Presented) The composition of claim 45, that is in a physical form selected from a concentrate, lyophilisate, powder, solution, or suspension.

59. (Previously Presented) The composition according to claim 45, wherein the drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt.

60.(Previously Presented) The composition of claim 45, wherein the drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid.

61. (Previously Presented) The method of claim 59, wherein the solubilizing agent is an amino acid and is L-arginine.

62.(Previously Presented) The method of claim 60, wherein the solubilizing agent is an amino acid and is L-arginine.

63.(Previously Presented) The composition of claim 61 that is suitable for parenteral administration.

64.(Previously Presented) The composition of claim 61 that is suitable for intravenous injection or infusion.

65.(Previously Presented) The composition of claim 62 that is suitable for parenteral administration.

66. (Previously Presented) The composition of claim 62 that is suitable for intravenous injection or infusion.

67.(Cancel)

68. (Currently Amended) A stable pharmaceutical comprising a therapeutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug or a pharmaceutically acceptable salt, solvate or derivative thereof selected from the group consisting of:

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

~~S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid 0.2 hydrate;~~

RS-(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [ij] quinolizine-2-carboxylic acid; and

a pharmaceutically acceptable solubilizing agent selected from the group consisting of basic amino acids, cyclodextrin, a cyclodextrin polymer or a derivative thereof; or a mixture thereof;

wherein the concentration of the drug that is maintained in solution with the solubilizing agent is above the practical limit of solubility of the drug as compared to the solubility of the drug when the drug is not solution with the solubizing agent, wherein the solution is a substantially isotonic aqueous solution at a physiologically compatible pH.

69. (Currently Amended) A method of treating a bacterial infection disease in a subject in need thereof which comprises administering to the subject, a pharmaceutical composition of claim 45 in a therapeutically ~~or prophylactically~~ effective dose.

70. (Previously Presented) The method of claim 69, wherein the composition is diluted in a pharmaceutically acceptable liquid prior to being administered to the subject.

71. (Previously Presented) The method of claim 69, wherein the subject is a human or animal subject.

72. (Previously Presented) The method of claim 69, wherein the daily dose of the benzoquinolizine-2-carboxylic acid antimicrobial drug is about 0.01 mg to 100 mg/kg.

73. (Previously Presented) The method of claim 69, wherein the said solubilizing agent is selected from the group consisting of amino acids, cyclodextrin polymers or a derivative thereof; or a mixture thereof.

74. (Previously Presented) The method of claim 69, wherein said composition is administered by intravenous injection or infusion.

75. (Previously Presented) The method 69, wherein the route of administration is parenteral.

76. (Previously Presented) The method of claim 69, wherein said composition is in a concentrate, lyophilized powder, solution or suspension form.

77. (Currently Amended) The method ~~composition~~ according to claim 69, wherein the composition comprises S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt.

78. (Previously Presented) The method according to claim 69, wherein the composition comprises S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid.

79. (Previously Presented) The method according to claim 77, wherein the solubilizing agent is an amino acid and is L-arginine.

80. (Previously Presented) The method according to claim 78, wherein the solubilizing agent is an amino acid and is L-arginine.

81. (Currently Amended) A process for preparing a pharmaceutical composition comprising mixing a pharmaceutically

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid;

~~S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid 0.2 hydrate;~~ and

RS-(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid; and

a pharmaceutically acceptable solubilizing agent selected from a the group consisting of basic amino acids, a cyclodextrin and, a cyclodextrin polymer; or a mixture thereof;

wherein the concentration of the drug that is maintained in solution with the solubilizing agent is above the practical limit of solubility of the drug as compared to the solubility of the drug when the drug is not in solution with the solubilizing agent, wherein the solution is a substantially isotonic aqueous solution at a physiologically compatible pH.

82. (Previously Presented) The process of claim 81, wherein said solubilizing agent is selected from the group consisting of amino acids, cyclodextrin polymers or a derivative thereof, or a mixture thereof.